FOR ADMINISTRATIVE USE

INTERIM REPORT OF EFFECTIVENESS OF POLIOMYELITIS VACCINE DURING 1958

This Report was prepared by the Poliomyelitis Surveillance Unit, Mario Pizzi, M.D., Jacob A. Brody, M.D., Harold W. Wylie, Jr., M.D., and Miss Helen Forester.

The effectiveness of the Salk vaccine can only be accurately determined by a comparison of the attack rates between vaccinated and unvaccinated groups as it was done during the Francis trials in 1954. Since then considerable attention has been paid to evaluate the results of the mass vaccination campaign which started in 1955, and to ascertain the duration of the protection conferred. As the number of vaccinated persons grew into the millions, however, accurate figures for the populations exposed to risk in the vaccinated and unvaccinated groups were no longer available. While some estimates based on sampling could be made, collateral information consisting of an analysis of epidemiological and laboratory findings had to be used. Although serological follow-up of vaccinated cases is, of course, an important tool, it is by definition limited in scope and coverage. Likewise the epidemiological analysis in the absence of knowledge of the populations exposed to risk can only supply indirect evidence. Still a good deal of knowledge concerning the evaluation of the vaccination program can be gained by a careful analysis of the data which have been collected by the Polio Surveillance Unit. These data are presented below under the following headings:

1. Comparison of Attack Rates Between Vaccinated and Unvaccinated Groups Based on Population Estimates
2. Secular Trends of the Disease
3. Age Specific Attack Rates
4. Proportion Paralytic by Vaccination Status
5. Vaccination Status of Cases in Epidemics
6. Vaccination Status of Deaths
7. Proportion Vaccinated in Paralytic Cases
8. Triply-Vaccinated Cases.

1. Comparison of Attack Rates Between Vaccinated and Unvaccinated Groups. The Polio Vaccine Activity Unit - USPHS - reports 49 million people in the nation are triply-vaccinated. The rate of paralytic cases among triply-vaccinated individuals compared with the entire triply-vaccinated population is 0.19 per 100,000. Similarly, the rate of less than triply-vaccinated paralytic cases to the less than triply-vaccinated population is 0.71 per 100,000. The ratio between these two rates is .27 and consequently the protection against paralysis is .73.

It should be noted that breakdowns by age are not available for the triply-vaccinated group and there are reasons to believe that the age distribution of the vaccinated and unvaccinated populations is somewhat different, particularly insofar as the youngest age groups are concerned. (These young children are precisely those with the highest attack rates and they will tend to increase the numerator in the unvaccinated group, thus increasing the estimate of the protection conferred by the vaccine.) More precise calculations will be made in the near future when age estimates will be available. In the meantime, however, it is believed that the margin of error is not too considerable and that the protection conferred can be estimated to be in the neighborhood of 70% again this year.

2. Secular Trends of the Disease. In Table I the poliomyelitis incidence for the period 1955-58 is presented. The consistently downward trend since the vaccination started is remarkable. Estimates for paralytic cases for the rest of the current year indicate that the total will be approximately 2,500 cases, about 20% higher than in 1957. This increase is basically due to the large epidemic in Detroit which so far accounts for about 20% of the cases in the nation and which occurred largely in unvaccinated individuals (Table IV). It could be argued, and rightly so, that a part of this downward trend since 1955 is just a reflection of the cyclical trend of the disease and that in 1942 - in the absence of any effective control measures - only 4,033 cases occurred. Only analyses of polio incidence in future years will enable us to judge to what extent the vaccine itself is responsible for this trend.

3. Age Specific Attack Rates. In the attached graph, the age specific attack rates for paralytic poliomyelitis for the period 1955-58 are compared with the 1952 rates. The "trough" noted for the 6-8 year olds in 1955 has persisted in the same group (now 9-11) through 1958. These are the children who received vaccination in the NFIP school vaccination program and are, therefore, a particularly well vaccinated group. This "trough" is interpreted as an indication not only of the protection conferred by the vaccine but also of its duration, now three years. The consistent decrease of the attack rates at all ages under 40 since 1955 should also be noted.

4. Proportion Paralytic by Vaccination Status. Table II A gives a breakdown of paralytic cases by vaccination status and age thus far in 1958 for which the vaccination status is known. This table confirms the data collected in 1956 and 1957 (Table II B) that the proportion of paralytic cases decreases with an increasing number of doses of vaccine. This inverse correlation is what one would expect for a vaccine which protects a proportion of those vaccinated against paralysis. To date in 1958, 71% of those receiving one dose were paralytic in contrast with 66% paralytic among those not vaccinated. This exception to the general trend clearly does not mean that one dose of vaccine predisposes its recipient to paralysis but can be explained by the fact that many individuals received their first dose during the polio season especially in epidemic areas, and hence were not sufficiently protected while being exposed to greater risk.

It is interesting to note that the downward trend with increasing doses is further accentuated in those paralytic cases which had received 4 doses (Table II C). Although the figures on which these percentages are based are small (21 cases in 1957 and 37 cases in 1958), this further decrease of the proportion paralytic among those receiving four doses is again consistent with the general assumption of vaccine effectiveness.

It should be noted that for any particular year the proportion of paralytic cases to total cases of polio varies. The proportion is, of course, influenced by the reporting of nonparalytic polio. Since ECHO or Coxsackie disease have frequently been reported as nonparalytic polio, variations in the annual reporting of these diseases make

comparisons between years of the proportion of paralytic polio cases quite difficult to interpret in the absence of accurate laboratory diagnosis. However, within a particular year, it is reasonable to assume that the ECHO and Coxsackie cases are randomly distributed among the non-vaccinated and those receiving 1-4 does and consequently, the comparison of the proportion paralytic is a valid one within each specified year.

It is difficult to visualize any other reason, except effectiveness of the vaccine, which will give this consistent downgrade pattern with the increasing number of doses of vaccine. An alarming indication that the protection conferred is diminishing will be manifested by the observation that the proportion of paralytic cases among triply-vaccinated individuals is approaching the proportion of paralytic cases in non-vaccinated individuals. This may first become apparent by a reversal during a given year of the proportion of paralytic cases receiving three doses as compared with those receiving two doses. So far, this has not been the case and the figures presented in these tables strongly indicate not only that the vaccine is effective but that its effect is persisting among those which have already received the three doses.

5. Vaccination Status of Cases in Epidemics. In Tables III and IV one can see that among paralytic cases 76% were not vaccinated in Texas, while 70% were not vaccinated in Michigan, and 89% were not vaccinated in New Jersey. Furthermore, in Michigan and New Jersey, the great majority of adequately vaccinated people had nonparalytic polio.

6. Vaccination Status of Deaths. Figures of deaths from polio since 1955, are presented in Table V. Out of the 76 deaths occurring so far in 1958, 52 had never been vaccinated, 4 had received only one dose; three, two doses; and 13 had received 3 does. Since there are no indications that the proportion of unvaccinated to triply-vaccinated individuals in the general population is of the order of 4 to 1 as in the deaths, and in fact the estimates of triply-vaccinated in the general population indicate that the ratio is closer to 2.4 to 1, the disparity between deaths in triply-vaccinated and unvaccinated cases points to protection conferred by the vaccine.

7. Proportion Vaccinated in Paralytic Cases. The data included in Table VI give the proportion of vaccinated (1-3 doses) among paralytic cases for 1956, 1957, and 1958. These figures give an indication of the vaccination status of the population since as the number of vaccinated individuals increases, so should the proportion vaccinated with paralytic polio increase. Theoretically, since the vaccine is not 100% effective should the entire population be vaccinated, all cases of paralysis would occur among vaccinated people. While a substantial increase of the proportion vaccinated is clearly noticeable between 1956 and 1957 (16 vs 30%) indicating a vigorous vaccination program at that time, the gains in 1958 have been negligible. The under 1 group appears to have been particularly neglected in 1958 with rather serious implications since the attack rates in this group are particularly high. Belief that the vaccinated population is not

increasing at a substantial rate is supported by figures published by the Polio Vaccine Activity Unit. As of May 1958, 49 million were triply-vaccinated and 12 million had had two doses. One year before, 24 million had had two doses while 32 million were triply-vaccinated. The gains that occurred in this period, therefore, were largely among people who increased from two to three doses rather than among the unvaccinated population. These facts seem to indicate that a special effort should be made next year to promote the vaccination program.

8. Triply-Vaccinated Cases. In Table VII the number of triply-vaccinated cases reported for 1956-58 is presented. As the number of triply-vaccinated individuals increases in the general population, so do the number of polio cases which are triply-vaccinated. The seven-fold increase of triply-vaccinated cases between 1956 and 1957 does not seem to have meaning other than as a reflection of the fact that millions of individuals completed their vaccination schedule in 1957.

SUMMARY.

In summary, all the data presented support the conclusion that the vaccine is highly effective. With the exception perhaps of the proportion paralytic among those unvaccinated and those receiving 1-4 doses, none of the other headings analyzed is conclusive in itself, but all of them strongly suggest that the efficacy of the vaccine is considerable. The duration of the protection conferred is indicated by the persistence of the "trough" in the age specific attack rates of those inoculated in 1955. Close surveillance is being maintained on the proportion of paralytic cases occurring among those triply (or more) vaccinated as compared with those having received 2 or less doses. An early indication that the vaccine is not holding will be a reversal of the proportion paralytic in these groups. At present, there seems to be no need for changing the current policy concerning vaccination schedule. Emphasis instead should be placed on complete vaccination of the population. It is disturbing to note that there are indications that the immunization program is slackening. A more concentrated effort is urgently needed.

The data from which these analyses were made are based on information received by the Polio Surveillance Unit from the states. We urge that the concerted effort to supply us with the necessary information be continued. In addition to following the over-all trends in polio, these data will enable us to contribute information in the following areas where current data is insufficient to provide adequate solutions:

(1) Ideal dosage schedule for initial course of vaccine and subsequent boosters

(2) Vaccine potency and persistence of protection

(3) Vaccine reactions and safety

(4) Specific populations which require vaccine or in which resistence to vaccination is occurring.

TABLE I

Poliomyelitis Incidence 1955 - 1958

	Total	Paralytic	Nonparalytic	Unspecified
1955	28985	13850	12453	2682
1956	15140	7911	6555	074
1957	5894	2159	2802	933
1958 (through October 4)	4067	1948	1521	598

TABLE II A

POLIOMYELITIS CASES REPORTED*, CONTINENTAL UNITED STATES
PERCENT PARALYTIC BY VACCINATION STATUS AND AGE

	Total Cases**	Cases with Vaccination Status Known	Cases Not Vaccinated	Vaccinated Cases by Number of Doses				Percent Paralytic By Number of Doses			
				Doses Unknown	1	2	3+	None	1	2	3+
< 1	71	64	56	-	4	3	1	88	-	33	-
1-4	564	522	354	8	41	46	73	83	88	70	58
5-9	424	386	158	8	32	44	144	62	59	41	28
10-14	210	193	59	9	8	35	82	54	50	17	28
15-19	143	130	61	2	9	17	41	61	56	53	22
20+	422	380	284	5	15	29	48	49	67	24	35
Unknown	18	12	8	1	1	1	1				
Total	1852	1687	979	33	110	175	390	66	71	42	34

* Preliminary reports to CDC January 1 - September 17, 1958.

** Omitted are 150 cases with paralytic status unknown.

TABLE II B

Percent of Reported Paralytic Cases

	Number of Doses of Vaccine			
	None	One	Two	Three or more
1956	59	47	32	23
1957	56	46	35	26
1958	60	71	42	34

TABLE II C

Fourth Dose

Percent of Reported Paralytic Cases

	Number of Doses of Vaccine				
	None	One	Two	Three	Four
1957	56	46	35	26	19 (21 cases)
1958	60	71	42	36	20 (37 cases)

TABLE III

1958 AGE DISTRIBUTION OF PARALYTIC POLIOMYELITIS
BASED ON EPIDEMIOLOGICAL REPORTS - TEXAS

AGE GROUP	NO. OF CASES	PERCENT OF TOTAL CASES	NO. OF CASES WITH NO SHOTS
0-4	132	65.6	109
5-9	29	14.4	15
10-14	6	3.0	2
15-19	6	3.0	4
20-24	6	3.0	4
25-29	10	5.0	9
30-34	7	3.5	5
35-39	3	1.5	2
40	2	1.0	2
TOTAL	201	100.0	152

TABLE IV

VACCINATION STATUS OF CASES IN
MICHIGAN AND NEW JERSEY THROUGH OCTOBER 8

	Paralytic	Nonparalytic
MICHIGAN		
Never Inoculated	164	116
Total Inoculated	69	163
1 Inoculation	30(1)	35(2)
2 Inoculations	21	41
3 Inoculations	18	86
4 Inoculations	-	1
NEW JERSEY		
Never Inoculated	68	20
Total Inoculated	9	14
1 Inoculation	3	1
2 Inoculations	4	4
3 Inoculations	2	9

(1) Including 8 cases with onset within 30 days of inoculation.
(2) Including 2 cases with onset within 30 days of inoculation.

TABLE V

Polio Deaths 1955 - 1958

	Deaths	Total Cases	Paralytic	Nonparalytic	Unspecified
1955	1043	28983	13848	12453	2682
1956	656*	15400	6708	5878	2814
1957	220*	5894	2159	2102	933
1958	76**	2600			

* Provisional - 10% sample of death certificates.
** Reported to PSU.

TABLE VI

PERCENT OF POLIOMYELITIS CASES REPORTED AS VACCINATED
Cases Reported through September 17, 1958, Compared with Cases Reported in 1956 & 1957

	Number of Cases*						Percent Vaccinated					
	Paralytic			Nonparalytic			Paralytic			Nonparalytic		
	1956	1957	1958**	1956	1957	1958**	1956	1957	1958	1956	1957	1958
< 1	452	146	55	144	40	9	9	14	11	9	20	23
1-4	2567	822	406	1160	395	116	18	27	29	35	51	47
5-9	1139	388	176	1602	739	210	33	49	48	57	74	71
10-14	766	194	67	952	412	126	24	46	55	42	75	79
15-19	504	132	60	585	290	70	9	28	39	15	42	66
20+	1782	490	175	1584	727	205	4	15	18	7	30	30
Total	7210	2172	939	6027	2603	736	16	30	31	32	54	56

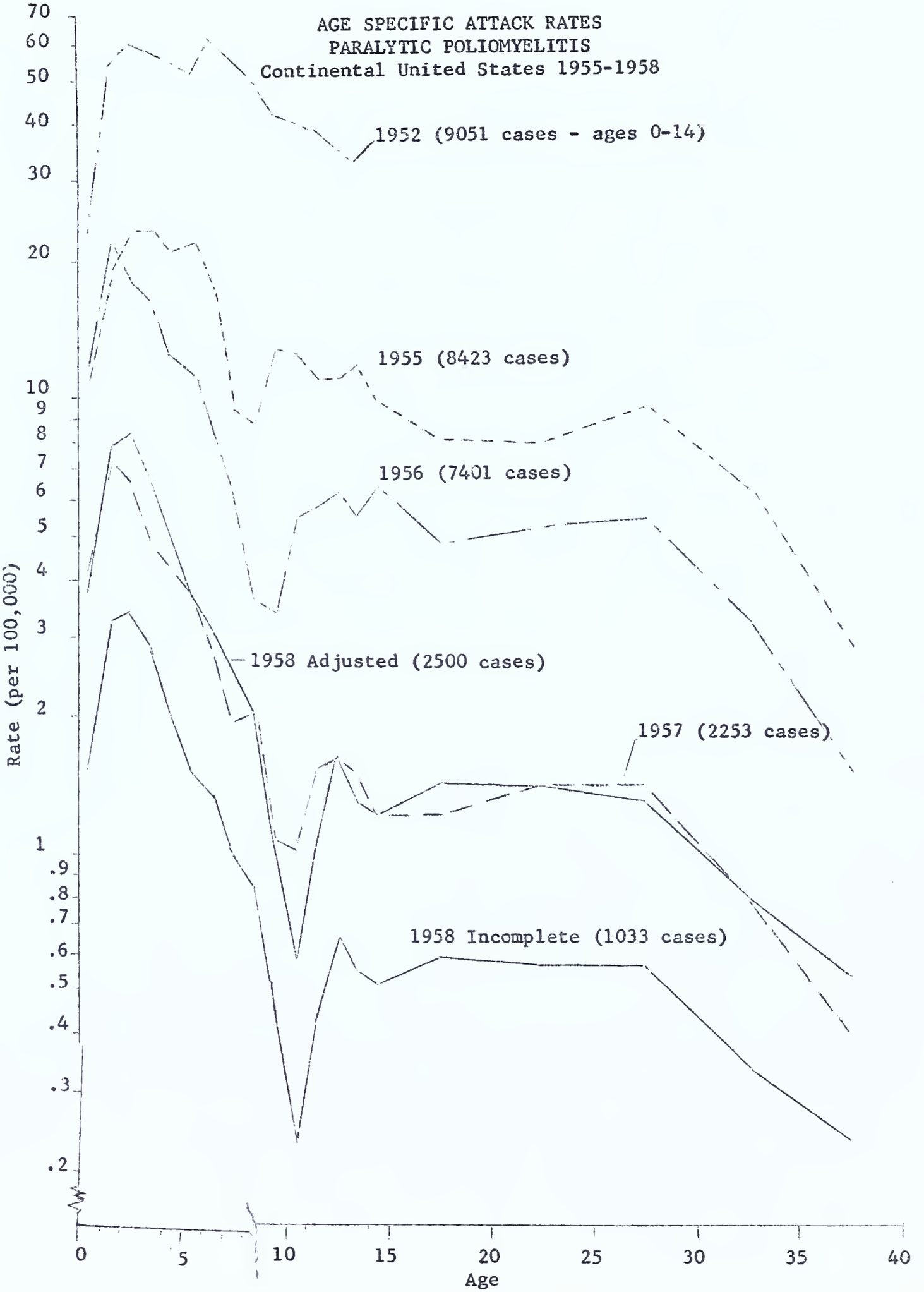
* Omitting cases with age, paralytic status and vaccination history unknown.

** Cases submitted to PSU from the Continental United States January 1 - September 17, 1958.

TABLE VII

TRIPLY-VACCINATED CASES 1956 - 1958

	Total	Paralytic	Nonparalytic	Unspecified	Deaths
1956	224	28	194	2	0
1957	796	207	588	1	3
1958 (through October 1)	535	166	364	5	13


AGE SPECIFIC ATTACK RATES
PARALYTIC POLIOMYELITIS
Continental United States 1955-1958
1952 (9051 cases - ages 0-14)
1955 (8423 cases)
1956 (7401 cases)
1957 (2253 cases)
1958 Adjusted (2500 cases)
1958 Incomplete (1033 cases)
Rate (per 100,000)
70
60
50
40
30
20
10
9
8
7
6
5
4
3
2
1
.9
.8
.7
.6
.5
.4
.3
.2
0
5
10
15
20
25
30
35
40
Age